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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,606	07/30/1998	PAN HONG JIANG	040388/0113	6230

7590

04/22/2002

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EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/22/2002

*Restart*  
*Date 5/24/02*

*31*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/077,606

Applicant(s)  
Jiang et al.

Examiner  
Patrick J. Nolan

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 18, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 43, 44, 46, 48, 49, 51-59, 61, 62, 64, 66, 67, 69, 72-79, and 82-109 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☒ Claim(s) 43, 44, 46, 48, 49, 51-59, 61, 62, 64, 66, 67, 69, 72-75, 77-79, 82-85A is/are allowed.
- 6) ☒ Claim(s) 76, 86, 90-92, 95, and 97-109 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: ☐ approved ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

Part III DETAILED ACTION

1. Claims 43, 44, 46, 48-49, 51-59, 61, 62, 64, 66, 67, 69, 72-79, 82-89 and newly added claims 90-109 are pending.
  2. Claims 43, 44, 46, 48-49, 51-59, 61, 62, 64, 66, 67, 69, 72-75, 77, 78-79, 82-85, 87-89, 93, 94 and 96 are allowed.
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3. The following new grounds of rejection are necessitated by Applicant's amendment filed 1-18-02

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 76, 86, 95 is rejected under 35 U.S.C. § 102(b) as being anticipated by Glass et al., (J. Cell Biology, Vol. 07, 1988), of record.

Applicant's arguments filed 1-18-02 have been fully considered but are not found persuasive.

Attorney's arguments does not replace evidence were evidence is required see MPEP 2145. Furthermore, the isolation of the protein on a SDS-PAGE gel, would be considered in an inert pharmaceutical carrier.

The prior art teachings anticipate the claimed invention.

5. Claims 92 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

SEQ ID NO. 1 is a nucleic acid not a protein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 76, 86, 90-91 and 97-109 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant has no written support for the subgenus claim inert pharmaceutical carrier as recited in claims 76, 86, 97-105.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103<sup>o</sup> and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 76, 86, 90, 91, 100 are rejected under 35 U.S.C. § 103 as being unpatentable over Glass et al., of record in view of Current Protocols in Molecular Biology (CPMB) and Lerner et al., newly cited

Glass et al., has been discussed supra. However, in addition Glass et al., teaches the isolated keratin protein K7, in a SDS-PAGE gel.

The claimed invention differs from the prior art teaching(s)

(only) in claims 90-91 and 100 by the recitation(s) of a method of stimulating an immune response from a patient with the isolated protein in an inert pharmaceutical carrier for parenteral administration. However, CPMB teaches the stimulation of antibody responses in mice with isolated proteins on SDS-PAGE gels. Lerner teaches the making of antibodies from known polypeptides, where the antibody can have predetermined specificity(see abstract and first paragraph, in particular). Lerner also teaches that antibodies are useful in studying the protein conformation of the protein (column 2, pg 594, in particular).

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One of ordinary skill in the art at the time the invention was made would have been motivated to use the isolated protein taught by Glass et al., in the method of CPMB and Lerner et al., because antibodies from pre-determined proteins are useful in studying protein confirmation of the protein. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

10. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

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*Patn J. Nolan*  
Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
April 21, 2002

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